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|-----------------|-------------|----------------------|---------------------|------------------|
| 09/594,387      | 06/15/2000  | Muthiah Manoharan    | ISIS-4390           | 9395             |

7590

07/30/2002

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EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 07/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/594,387

Applicant(s)

MANOHARAN, MUTHIAH

Examiner

Sean McGarry

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-19,21-29,31,32,34-44,46 and 48-57 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1,2,5-19,21-29,31,32,34-44,46 and 48-57 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Applicant has addressed the examiners concerns of applicants IDS filed 2/10/2000 by stating in footnote (2) that at the time it was not required that a copy be supplied. It is requested that applicant provide the examiner a copy of the requirement at the time the IDS was filed since the examiner has access to only the latest versions of the MPEP. It is noted that those applications not yet considered are not available for the examiner to review at the time of the instant Official Action.

K.T.  
7/29  
Claims 1, 2, 5-19, 21-29, 31, 32, <sup>34</sup>24-44, 46, 48-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 09/334,130. Although the conflicting claims are not identical, they are not patentably distinct from each other because of those reasons set forth in the provisional rejection in the Official Action mailed 10/3/01. It is noted that applicant has argued the previous provisional rejection drawn to statutory double patenting in the response filed 1/22/02 and that rejection has been withdrawn.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 5-19, 21-29, 31, 32, 34-44, 46, and 48-57 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons set forth in the Official Action mailed 10/3/01.

Applicant's arguments filed 1/22/02 and 5/9/02 have been fully considered but they are not persuasive. Applicant argues that the above rejection is actually challenging the adequacy of enablement of the claimed invention. Applicant argues that the application is supported by the claims as originally filed. Applicant argues that page 12, originally filed claim 17 and page 13 of the specification as originally filed discloses the genus of "arylpropionic acids" and "serum and vascular proteins". Applicant then argues that the scope of the claims has not been broadened and therefore the claims must have an adequate written description. Applicant disclosure does not, however describe an adequate number of species of arylpropionic acids and serum and vascular protein combinations such that one in the art would recognize that applicant was in possession of the full scope of the claimed invention. The invention is specifically drawn to oligomers conjugated to an arylpropionic acid that interacts with a protein in general and then is drawn to narrower embodiments. The instant specification does not provide one in the art what structural features, for example, of an arylpropionic acid allows binding to proteins in general and more specifically to different specific serum and vascular proteins. The instant specification has disclosed only specific arylpropionic acids that bind to albumin. From this disclosure, one in the art would not recognize that the structural features that allow binding of a vast array of arylpropionic acids to a wide array of proteins, serum protein, or vascular protein have been adequately described.

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One in the art would not recognize the disclosure of the limited number of species is representative of the genus claimed. Although applicant has "disclosed the genus of arylpropionic acids" by a general statement that the genus is included, the disclosure of what arylpropionic acids that possess the attributes (eg chemical properties or specific structures) that are required for the instant invention ( those attributes that allow binding to a protein, serum protein or vascular protein , for example) have not been described.

Claims 1, 2, 5-19, 21-29, 31, 32, 34-44, 46, and 48-57 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for that scope indicated in the previous Official Action mailed 10/3/01, does not reasonably provide enablement for the scope claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is maintained for those reasons set forth in the Official Action mailed 10/3/01.

Applicant's arguments filed 1/22/02 have been fully considered but they are not persuasive. Applicant has argued that the rejection of record does not provide evidence indicating a reason to doubt the enablement of the instant invention and that the arguments presented in the rejection has failed to provide evidence. Applicant has argued that the rejection appears to require an example for every arylpropionic acid. The rejection does not so require but discusses the failure of the specification to provide adequate examples or guidance that would correlate to the practice of the scope of the invention instantly claimed without undue trial and error experimentation. Applicant

argues that the rejection of record has not established why some arylpropionic acids are enabled and some are not. It is noted that the rejection provide detailed reasoning why the scope of the invention has been found to be not enabled. It is noted that applicant arguments do not address the specific arguments set forth in the rejection such as those in section (c.) and (d.) of the rejection.

Claims 1, 2, 7-11, 14-19, 21, 26-28, 34, 39, 40, 41, 42, 55, and 56 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hale et al.

Applicant has argued that the Hale patent fails to teach one in the art to use oligonucleotides and arylpropionic acids as claimed. It is noted however that it is not required that the anticipatory reference teach the use of the genus claimed. The reference discloses an oligonucleotide and naproxen, which is a species of the genus claimed.

Any rejection made in the previous Official Action (mailed 10/3/01) and not repeated herein is withdrawn.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM  
July 29, 2002



SEAN MCGARRY  
PRIMARY EXAMINER